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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,627	09/26/2002	Mark Anthony Fernance Kendall	KEMP002	8277

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EXAMINER
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WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

4

<b>Office Action Summary</b>	Application No. 10/031,627	Applicant(s) KENDALL ET AL.	
	Examiner Catherine N. Witczak	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25, 27-41 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 8, 35 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-25, 27-34, 36, 37 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Wavy signature* 10/28/07

Art Unit: 3767

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not provided sufficient detail as to how the invention is constructed and arranged so as to establish a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section upstream of the primary shock wave and how/what structure allows for the particles to be substantially wholly entrained in the substantially shockwave-free quasi-steady flow for the duration of time that the particles are in the duct section.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 9-25, 27-34, 36, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by BELLHOUSE et al. (US Patent No. 5,630,796).

Bellhouse discloses a needless injection device and method of using the device including a rupturing membrane closure means (col. 8, ll. 1-5), substantially constant diameter driver chamber

W

Art Unit: 3767

(upstream of rupturable membrane 34), substantially constant diameter duct section connected to driver chamber to receive gas therefrom, (constant diameter is within distal section of duct section, fig. 1, wherein the term substantially constant cross-sectional diameter is not fully defined by the specification and therefore since the cross-sectional diameter does not vary significantly the diameter of Bellhouse is seen to be substantially constant), dose of particles P upstream of closure means 34, fig. 8, divergently contoured nozzle 38 (downstream of duct) through which a quasi-steady flow travels, a quasi-steady gas flow that is substantially free of shockwaves, whereby the device generates shock waves and reflection waves upon rupturing the membrane. A bleed hole is disclosed to provide the pathway from pressurized gas to the driver chamber and a bleed valve is understood in the art to be of small size that it would substantially decouple the driver chamber with pressurized gas source (col. 4, line 62 - col. 5, line 2). Nozzle areas are chosen with respect to driver chamber pressure to be correctly expanded (col. 5, II. 22-33; col. 5, II. 60-65; col. 6, II. 5-7). Different gases are selected to give different velocities (col. 6, II. 5-7).

Some limitations recited in the claims are considered inherent. Establishing quasi-steady flow upstream of shock waves, claims 1, 5, 20, entraining and accelerating particles in quasi-steady flow, claims 1, 20, initiating a starting process when shock wave reaches duct section end, claim 2, 21, producing a secondary shock wave behind primary shock wave, claim 4, uniform velocity distribution over a cross-section, claims 7 & 28, movement of closure means col. 8 lines 1-31, claims 11, 32, no oblique shocks waves within the divergent nozzle, claims 12, 31, initiating (u-a) wave at duct end, claim 14, quasi-steady flow upstream of (u-a) wave, claim 15, expansion wave traveling upstream of membrane closure means, claim 16, and terminating quasi-steady flow when reflected expansion wave passes out of the device, claim 18 are considered inherent functions resulting from the generation of shock waves by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section, and divergent nozzle.

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Art Unit: 3767

The prior art discloses the same or similar structure recited in the claims and described in the specification with respect to fig. 5 and this similarity is the basis that the prior art device will inherently function as the claimed device and produce the associated waves and effects in use with shock waves. If Applicant argues that these claimed functions are not inherent Applicant should submit evidence that the prior art devices do not inherently possess these characteristics. See MPEP 2112, 2112.01, 2112.02.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over BELLHOUSE '880 as applied to claim 36 above, and further in view of BELLHOUSE '478. Bellhouse '880 teaches the claimed invention except for scoring the rupturable. Bellhouse '478 teaches scoring a rupturable membrane in order to limit shedding fragments (col. 8, 11.52-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '478 in the device of Bellhouse '880 in order to facilitate rupturing the membrane preventing unwanted material from traveling to the target site.

### *Response to Arguments*

Applicant's arguments filed 8/16/2007 have been fully considered but they are not persuasive. Applicant argues that the amended claims distinguish the application over the prior art. However, Examiner notes that although Applicant has claimed specific properties of the invention, there is no enabling description of how the device is made/used to produce these results. The prior art of record

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Art Unit: 3767

meets the structural limitations of the claim, furthermore Applicant admits that certain features of the prior art do indeed disclose claimed limitations (that Bellhouse creates quasi-steady flow), but Applicant then refers to Figures within their own application to come to the conclusion that "all flow downstream of the shockwave 14 is not quasi-steady" without providing any detailed explanation as to how the claimed device manages to overcome this difference.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witzak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keyin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cw



10/28/08

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

